

A novel fusion imaging system for endoscopic ultrasound

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ABSTRACT

Background and Objective: Navigation of a flexible endoscopic ultrasound (EUS) probe inside the gastrointestinal (GI) tract is problematic due to the small window size and complex anatomy. The goal of the present study was to test the feasibility of a novel fusion imaging (FI) system which uses electromagnetic (EM) sensors to co-register the live EUS images with the pre-procedure computed tomography (CT) data with a novel navigation algorithm and catheter. **Methods:** An experienced gastroenterologist and a novice EUS operator tested the FI system on a GI tract bench top model. Also, the experienced gastroenterologist performed a case series of 20 patients during routine EUS examinations. **Results:** On the bench top model, the experienced and novice doctors reached the targets in 67 ± 18 s and 150 ± 24 s with a registration error of 6 ± 3 mm and 11 ± 4 mm, respectively. In the case series, the total procedure time was 24.6 ± 6.6 min, while the time to reach the clinical target was 8.7 ± 4.2 min. **Conclusions:** The FI system is feasible for clinical use, and can reduce the learning curve for EUS procedures and improve navigation and targeting in difficult anatomic locations.

Key words: Electromagnetic (EM) guidance, endoscopic ultrasound (EUS), fusion imaging (FI), hybrid imaging, pancreatic lesions

INTRODUCTION

The accurate diagnosis and staging of abdominal and thoracic diseases are possible with endoscopic ultrasound (EUS) systems that generate high resolution images of target organs in various gastroenterological disorders.^[1] Moreover, linear EUS systems allow EUS-guided fine needle aspiration (FNA), and cytological and/or micro-histological diagnosis, especially for pancreas and lymph nodes.^[2]

Although they offer improved imaging and have been commercially available from the beginning of the 1980's,

the EUS systems have been hesitantly adopted by some gastroenterologists due to a long learning curve, small field of view, uncertain ultrasound interpretation, and difficult navigation.^[3] EUS is still underused by the large worldwide community of gastroenterologists and pulmonologists despite consistent efforts to improve the learning curve through the use of supervised human procedures in reference centers, computer-based simulators, or live animal models.^[4-7] In particular, the performance of EUS-FNA is still limited to tertiary referral centers, although it has a significant clinical impact to the management of the patients, especially in pancreaticobiliary and mediastinal disorders.^[2] As EUS strongly depends on the training, skills, and experience of the endoscopist, the development of better navigation techniques and recognition of anatomical landmarks remain critical for a wider adoption of this technology.^[8]

To improve navigation of medical instruments inside the body, fusion imaging (FI) systems use electromagnetic tracking and co-registration of live imaging such as

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transabdominal ultrasound (US) and high resolution, pre-procedure imaging such as computed tomography (CT) or magnetic resonance imaging (MRI). FI procedures which combine EUS and CT might allow a better visualization of lesions, and possibly improve the selection and targeting of lesions for EUS-guided FNA in the pancreaticobiliary and mediastinal areas.^[9,10] Beside navigation, the three-dimensional (3-D) anatomical reconstruction might further enhance EUS examinations, through a better visualization of spatial relations of examined lesions (targets), allowing future offline interrogations of the captured data volume.^[11] Linear EUS and EUS-FNA are especially difficult to perform due to the complexity of the anatomy and the small size of the probes, but a prototype 3-D visualization of the linear EUS enhanced the evaluation of vascular involvement in pancreatic lesions.^[12] Thus, the addition of an automated 3-D acquisition technique might be desirable for future linear EUS transducers, as compared to the currently available free-hand techniques.

At present, most of the commercially available FI systems are indicated for guiding US and straight (rigid) biopsy needle procedure rather than a flexible probe in a complex 3-D anatomy during EUS procedures. To address this limitation, in the present study, we tested the feasibility of a newly-developed FI system to guide the EUS procedure by superimposing the live EUS probe and the pre-procedure CT scan in an artificial model of abdominal/mediastinal targets, and in a case series of 20 patients during routine EUS examinations.

MATERIALS AND METHODS

FI system

The FI system uses the Aurora V2 electromagnetic tracking system (Northern Digital Inc., Ontario, Canada) with a planar field generator (which generates a 500 mm × 500 mm × 500 mm magnetic field) for spatial positioning, connected to a computer that runs our proprietary navigation software application, a custom-made navigation catheter placed inside the endoscope's working channel, as well as one Aurora 6DOF, 25 mm active marker disc (part number 610066, Northern Digital Inc., Ontario, Canada) placed on the patient's chest [Figure 1]. The navigation catheter was developed from a standard FNA catheter to which we replaced the biopsy needle with Aurora Mini 6DOF electromagnetic sensor 1.8 mm × 9 mm (Part Number: 610029, Northern Digital Inc., Ontario, Canada) such that suction and mucosal apposition of the probe

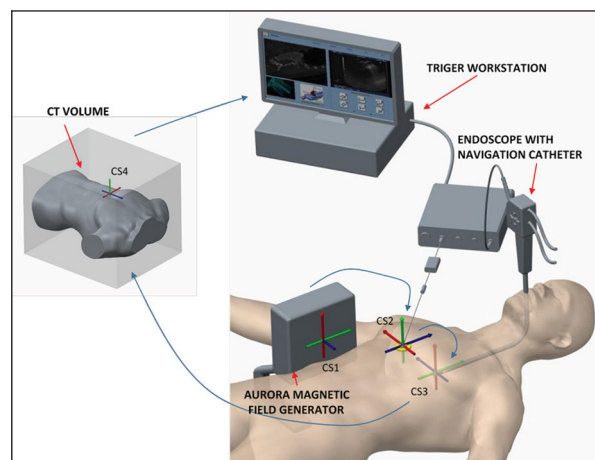


Figure 1. The FI system components. There are four coordinate systems (CS1-4) used during registration to provide the framework for moving between the pre-operative CT and the intraoperative EUS imagery: between the image coordinates and the navigation catheter, and between the navigation catheter and the 3-D display

during EUS examinations was still possible. The electromagnetic sensor reaches the tip of the catheter tube and is sealed from contact with the patient's tissue. Both the navigation catheter and the active marker contain electromagnetic sensors with 6 degrees of freedom (DOF) incorporated in them. After reaching the target, the EUS is fixed in place and the navigation catheter is retracted and replaced with a FNA needle. A conventional linear EUS scope Conventional linear Pentax EG-3870UTK EUS scope (Hoya Corporation, Tokyo, Japan) and the corresponding ultrasound system Hitachi EUB-5500 ultrasound system (Hitachi-Aloka, Tokyo, Japan) were used for all the procedures.

FI navigation software

The navigation software allows the operator to: Load the CT scans, create the 3-D model of the patient anatomy, co-register the EUS patient space with the CT space, identify and navigate towards the target, and make fine adjustments to the registration. The navigation interface includes several windows for registration, fine calibrations, dual visualization of the EUS image, and its corresponding virtual section through the CT volume [Figure 2]. During the EUS procedure, the navigation is facilitated by a real-time overlay of the endoscope tip position on the virtual volume of the patient anatomy. A registration correction is executed automatically by the system, to correct for the patient's movement.

The registration and navigation functions of the FI software were developed using Insight Segmentation and Registration Toolkit (ITK), Visualization Toolkit (VTK)

and Image-Guided Surgery Toolkit (IGSTK) open-source libraries, to synchronize the information from two imaging modalities.^[13-15] Briefly, the CT and the endoscope's tip position are co-registered in real-time using the spatial positioning data provided by navigation catheter and the active marker, and a computer algorithm based on a closed-form solution of absolute orientation using unit quaternions.^[16] Compared to other mathematical methods like orientation matrices or Euler angles, the quaternions have simpler formulas (i.e., easier to implement) and give smaller errors during successive rotations while aligning the CT scans with the live EUS image.^[16]

Bench top testing

The feasibility test for the FI system was performed using a bench top phantom, which represents an artificial model of abdominal/mediastinal targets [Figure 3]. The phantom is a 24 cm × 17 cm transparent plastic box with a 2.5 cm wide flexible rubber tubing fixed inside to represent the digestive tract, and five spherical “tumor” targets, from a CT opaque material, 6-18 mm in diameter and glued on the outside of the rubber tubing at different depths inside the tubing [Table 1]. The phantom box has an

opening on its side of the same diameter as the rubber tubing through which the endoscope probe can enter the “digestive tract”. The active marker is placed outside the opening and the distance to the “tumor” targets is measured during the bench top testing [Table 1, Column 2]. The phantom was brought in the operating room and fixed on the same endoscopy table where the patients are placed during the EUS procedure. The spatial position of the targets was acquired using the Aurora system by touching them with a 6DOF straight tip standard probe (Northern Digital Inc., Ontario, Canada, part number 610065). The same CT system (Siemens Somatom Sensation 4 slices CT system, Siemens Medical Systems, Erlangen, Germany) was used to scan both the patients and the phantom. The registration error is the absolute distance between the position of the endoscope tip and the target for the advanced user, E_AU, and beginning user, E_BU [Table 1].

CASE REPORT

A case series of 20 patients was performed during routine sequential CT and EUS procedures within the clinical work-up of patients with various pancreaticobiliary and mediastinal diseases. The fusion CT-EUS session was performed simultaneously with the EUS examinations based on EM navigation and co-registration of the real-time EUS image with pre-procedure CT sections. All procedures were performed according to the guidelines of the World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Humans.

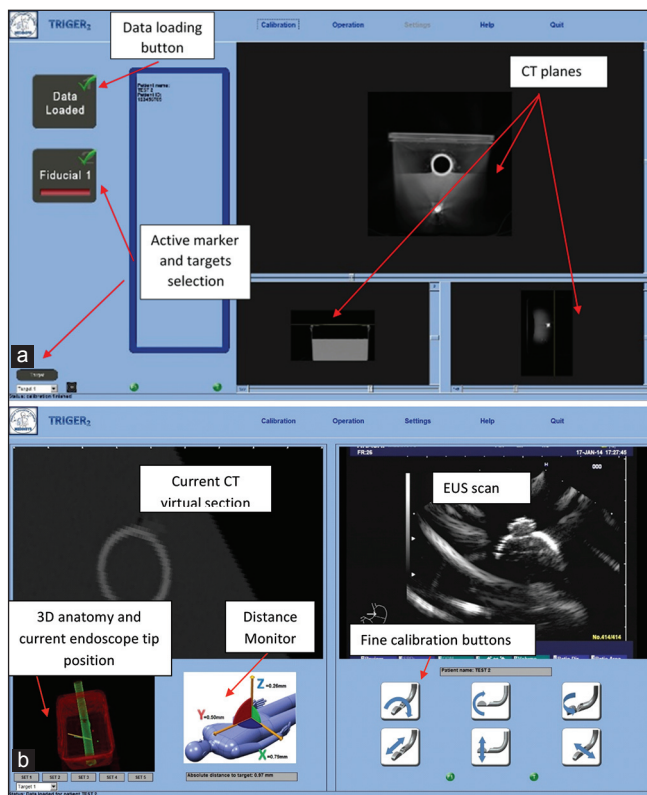


Figure 2. The FI system interface during the phantom feasibility testing procedure: (a) active marker and target selection window, and (b) navigation window for hybrid imaging CT-EUS procedure

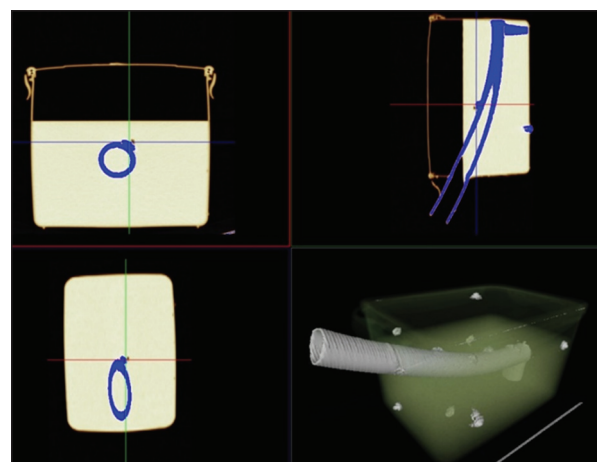


Figure 3. The 3-D reconstruction of the GI tract phantom model from CT scans. External white registration markers are visible on the box walls. Several tumor markers are positioned on the central (white) tubing which represents the GI tract

All patients signed an informed consent for the EUS examinations, while the procedures were following standard clinical guidelines, with additional software 3-D reconstructions of the CT images that did not alter their diagnosis and treatment management.

Ten women and 10 men 57.4 ± 13 years old have been included in the case series [Table 2]. Less than 24 h prior to the EUS-FI procedure, the patients were examined by contrast-enhanced CT for mediastinal and pancreatobiliary indications, at the recommendation of their attending doctor, independent of this study. The indications for the EUS procedure were suspicion of pancreatic masses (8 patients) or lymph nodes (1 patient), as well as suspicion of mediastinal masses (5 patients) or lymph nodes (1 patient). Five additional patients were

examined for suspicion of common bile duct stones and previous episodes of acute cholangitis/pancreatitis. The EUS procedure was performed with propofol sedation administered under the supervision of the anaesthesiologist. The two images (CT and EUS) were co-registered and visualized in real-time using the FI system [Figure 4]. There were no clinical complications reported during the procedures or follow-up for any of the patients. Hence, the clinical management of the patients was not changed in any way by the FI procedure.

The EUS-FI procedure

For the EUS+FI procedure, a personal computer was connected via an S-video cable to the ultrasound scanner for EUS image acquisition and a universal serial bus (USB) cable to the electromagnetic tracking system

Table 1. FI feasibility test results performed on the GI tract phantom

Target	E_AU (mm)	T_AU (sec)	Calib. Op.	Rot	Trans	E_BU (mm)	T_BU (sec)	Calib. Op.	Rot	Trans
T1	3.4	48	2	1	1	6.6	123	4	2	2
T2	4.1	65	4	2	2	8.2	162	5	2	3
T3	5.2	52	4	2	2	10.1	136	6	3	3
T4	6.6	82	5	3	2	12.8	146	5	3	2
T5	10.2	90	3	2	1	16.1	185	7	3	4
Mean	6	67	3.6	2	1.6	11	150.4	5.4	2.6	2.8
STDEV	3	18	1	1	1	4	24	1	1	1

Target: Individual targets on the phantom tubing, E_AU: Calibration error for the advanced user, T_AU: Procedure time for the advanced user, E_BU: Calibration error for the advanced user, T_BU: Procedure time for the advanced user, Calib. Op.: Total number of calibration operations for each procedure, Rot: Number of rotations performed during navigation toward a target, Trans: Number of translations performed during navigation toward a target

Table 2. Case series summary for the EUS/CT procedure using the FI system

Sex	Age (yrs.)	Diagnosis	Fusion procedure time (min)	Time to target (min)	Distance to target (mm)	Visual orientation/calibration error
F	71	Peripancreatic LN	32	8	22	Low
F	67	Mediastinal tumor	25	12	11	High
F	54	Normal	18	9	8	Low
M	74	Normal	22	6	18	Medium
M	56	Pancreatic carcinoma	28	14	10	Low
M	78	Mediastinal LN	40	5	5	Low
M	57	Mediastinal tumor	17	6	4	Low
F	30	Papillary carcinoma	15	7	5	Low
M	44	Pancreatic carcinoma	22	12	22	High
M	42	Normal	21	17	17	High
F	47	Pancreatic cystic mass	21	9	3	Low
F	42	Normal	21	7	4	Low
F	53	Pancreatic cystic mass	28	5	22	Medium
F	51	Pancreatic NET	21	8	4	High
F	63	Pancreatic carcinoma	32	5	11	High
B	61	Normal	31	5	18	High
B	77	Mediastinal tumor	22	14	6	Low
B	53	Pancreatic cystic mass	21	16	7	Low
F	56	Mediastinal tumor	35	1	2	Low
B	72	Mediastinal tumor	19	8	1	Low
Mean	57.4		24.6	8.7	10	
SD	13.0		6.6	4.2	7.2	

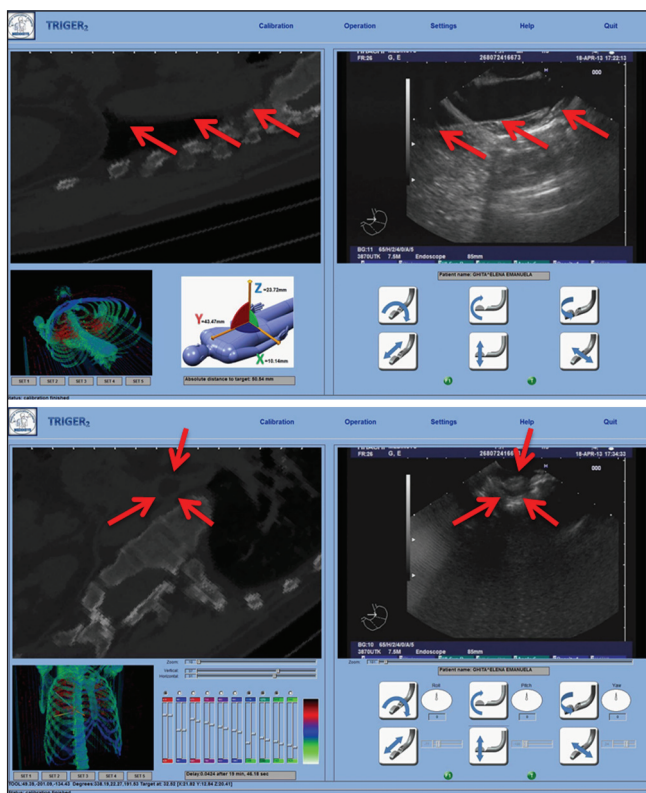


Figure 4. (a) Representative screen shot of the FI system interface during an EUS-CT procedure in a patient with A - co-registration at the level of the descending aorta (red arrows), imaged from the esophagus; and (b) co-registration at the level of a small submucosal tumor (lipoma, red arrows), imaged from the terminal esophagus. Beside the vascular structures and/or target structure (tumor), there is no correspondence in between anatomical structures visible on EUS and CT windows, as the lung tissue (containing air) and bony structures (spine) are visible only on CT, while EUS has a limited field of view

(ETS). The magnetic field generator was mounted on the endoscopy table close to the patient, and one active EM marker was placed on the patient’s skin on top of the xiphoid bone. The navigation catheter was advanced inside the endoscope’s working channel with its tip close to the ultrasound probe of the endoscope and was connected to the Aurora system. For the phantom study, the box was placed at the same location as the patient’s chest for consistency of the navigation parameters.

After the imaging instruments are connected to the computer, the software application is launched and the patient CT data is loaded and displayed. On the CT images, the physician will identify the active marker on the patient skin for initial registration [Figure 4a] and will mark the anatomical target. A 3-D volume of the patient is automatically created from CT scans and can be adjusted for a better tissue and tumor identification [Figure 4b]. If additional positioning adjustments are

necessary for a more accurate CT-EUS registration, the physician can lock the EUS image and navigate through the CT stack to find a similar virtual section using the rotation and translation buttons [Figure 2b]. The physician can further improve the registration by selecting an anatomical landmark (i.e., the iliac trunk) on the CT images, in addition to the active marker on the patient’s chest.

The following parameters were recorded for each EUS procedure with FI:

- CT and EUS images of the major vessels and target lesion.
- Final diagnosis based on the results of the EUS-guided FNA.
- Time to reach the lesion (target).
- Total time of the CT-EUS fusion imaging procedure.
- Distance to target (the distance between the tip of the sensor and target).
- Visual Orientation/calibration error (recorded as low, medium, high), based on the alignment of big vessels and other anatomical landmarks (aorta and celiac trunk; left liver lobe; left adrenal gland; pancreatic body and splenic vessels).
- Precision of reaching the target lesion (recorded as low, medium, high) defined as the proximity of the target lesion pre-defined on CT, when the target lesion was visualised during EUS navigation.

Precision of simultaneous CT-EUS visualisation (recorded as low, medium, high) defined as the simultaneous EUS-CT visualisation of the target lesion, after the co-registration.

Statistical analysis

The statistical analysis was performed in Microsoft Office Excel (Microsoft, Redmond, Washington, USA). All FI + EUS procedure parameters in the phantom and case series are reported as the mean ± standard deviation.

RESULTS

Bench top phantom testing

Two medical doctors, an advanced gastroenterologist with extensive EUS experience and a beginner EUS operator, performed the bench top FI testing independently [Table 1]. The doctors started by loading the CT data of the phantom, and choosing the active marker and target locations. They performed the EUS procedure using the FI navigation sensor as described above, with the goal of reaching every tumor target

with the endoscope tip using only the hybrid CT/EUS images for guidance. When they considered that CT and EUS images are similar, the spatial position of the navigation catheter sensor was recorded. If during navigation, the doctors observed differences between EUS and CT images, they performed fine adjustments of the registration by rotating or translating [Table 1, Calib. Op] the CT image using a 3-D mouse. The experienced doctor reached the targets with an average registration error of 6 ± 3 mm, an average time to reach a target of 67 ± 18 s, and with 4 ± 1 calibration operations (2 rotations and 2 translations) per target. Comparitvely, the beginner doctor registered an 11 ± 4 mm error, 150 ± 24 s to reach the target and 5 ± 1 operations (3 rotations and 2 translations) per target.

Case series study

All the human procedures were performed by the experienced gastroenterologist. Figure 4 shows an example of the FI screen shot at the time of co-registration. The doctor navigated towards major vessels such as the descending aorta and other anatomical landmarks [Figure 4a], or towards the target tumor lesions [Figure 4b]. Due to an unstable position at the level of the gastroesophageal junction, as well as air artifacts, the EUS image was sometimes unstable, while the hyperechogenic appearance on EUS and hypoenhanced appearance on CT were evident.

The total procedure time for the EUS-CT fusion imaging with the FI system was 24.6 ± 6.6 min, while the time needed to reach the target was 8.7 ± 4.2 min. The distance between the navigation sensor placed inside the biopsy channel of the echo-endoscope and the pre-established target from the CT scans was 10 ± 7.22 mm. The visual orientation/calibration error was qualitatively evaluated as low in 12 patients and medium/high in 8 patients. The precision of lesion targeting and precision of simultaneous CT-EUS visualisation was also evaluated qualitatively as high in 16 patients and medium/low in 4 patients. Whenever co-registration was lost during the procedures, it was re-aligned based on the aorta and celiac trunk appearance in both EUS and CT images.

DISCUSSION

The FI system improved the precision of reaching tumors by combining the detailed CT scan with live (real-time) EUS imaging without modifying the standard EUS procedure. The navigation catheter was designed

to fit through the EUS scope-working channel and not be in direct contact with the patient's body. The doctor used the FI system to bring the EUS probe in the proximity of the target, then removed the navigation catheter, inserted the biopsy needle catheter, and proceeded with the standard EUS-guided FNA procedure. A similar system was developed but the navigation catheter was taped on the outside of the endoscope's working channel.^[17] Since this system is not commercially available, a direct comparison with our system was not possible.

Navigation inside the human body involves repeated rotations and translations of medical instruments, making computerized algorithms difficult to develop. Traditionally, matrix-based coordinate system algorithms are used for 3-D navigation systems.^[15,18] These algorithms work well during translations or simple rotations but we found they are not appropriate for the complex 3-D navigation in the gastrointestinal environment. Instead, we developed a novel algorithm based on the quaternion method, which has the advantage of maintaining the 3-D orientation during complex rotation and translations. Therefore, the navigation procedures involved a limited number (4-5) of rotations and translations with no loss of reference system orientation.

Normally, a long learning curve is necessary for EUS procedures even for experienced gastroenterologists and surgeons.^[3] In our study both the experienced and novice doctors were able to use the FI system in the phantom, using a similar number of operations (4 *vs.* 5 rotations and translations) and obtaining a less than 15 mm error (6 mm in the case of the advanced user). The novice doctor needed approximately double the time to navigate to the target, probably due to the ability of the experienced doctor to manipulate the endoscope and align the CT section and EUS images faster, while the novice doctor was new to the EUS and CT procedures.

Based on the experienced gastroenterologist's evaluation, the EUS-CT fusion imaging procedure did not add significant extra-procedural time, although the co-registration had to be re-aligned several times during the procedures. The major advantage of using the system was the ability to reach the target lesions using concomitant EUS and CT imaging techniques, which allows the doctor to navigate towards (or away) major vessels and other anatomical landmarks [Figure 4a], as well as to visualize the contrast-enhanced EUS and CT

appearance of the target lesions [Figure 4b]. As the calibration/orientation error was evaluated as medium/high in 40% of the patients, further improvements for the co-registration will be performed using a flexible endoscope in the setting of a complex anatomy (especially in the pancreaticobiliary region). Nevertheless, the precision of simultaneous CT-EUS visualisation was evaluated as high in 80% of cases, suggesting that the system is more accurate at depicting the target (tumor) lesion appearance using two complementary imaging methods (EUS and CT/MR), as opposed to navigating in the setting of moving anatomical landmarks during the progression of the endoscope in the GI tract.

The main limitations of using co-registration between the pre-procedure and the live imaging are spatial alignment and difference in imaging characteristics. Internal organs usually change their anatomical position due to various physiological factors (i.e., patient position, breathing, food and liquid ingestion, endoscope manipulations, etc.). On the other hand, the same structures are not visible in both imaging modalities [Figure 4]. Consequently, there could be differences in position between the live EUS image and the CT/MR scans. To address this issue, in our system the co-registration can be manually updated during the examination, based on nearby anatomical vascular structures, which retain their shape and location. To accomplish this important correction in alignment, we used an improved mathematical algorithm, which allows faster feedback and better coordinate system alignment during the procedure. Due to the fact that the major aim of this preliminary study was to test the feasibility of real-time magnetic navigation fusion for EUS-CT images during ongoing EUS examinations, we choose not to alter the clinical management through comparative design studies.

The difficulty to detect a biological organ might be diameter-dependent for very small targets. As EUS is a high-resolution technique, we could visualize and navigate to all “tumor” targets in the phantom between 6 and 18 mm in diameter, for both EUS and CT. Nevertheless, targets smaller than 6 mm are difficult to identify on the CT image, and therefore are harder to navigate to. A further improvement of the distance-to-target error could be accomplished by operator training, including navigation techniques (optimum rotation and translation sequence to reach a target) as well as instructions for alignment of imaging modalities (CT and EUS) prior and during the procedure.

CONCLUSION

In conclusion, FI based on EUS-CT co-registration is feasible and accurate. FI based on EM navigation will increase detection and characterisation of lesions through simultaneous CT/MR visualisation of the EUS target. It can also be used as a training tool and will possibly reduce the learning curve for EUS procedures and increase user confidence by improving navigation to CT/MR determined targets. Future studies will address the clinical and training benefit of the combined EUS-CT fusion systems with emphasis on EUS-FNA.

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